ALFRED MANN FOUNDATION

FAX TRANSMISSION

December 6, 2005

TO: Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

FAX #: 571-273-8300

FROM: Oleh Zajac
Alfred Mann Foundation

FAX #: 661-702-6710

Total number of pages 12 (including cover page).

Applicant:	Jiang	**Art Unit:**	1745
Serial No.:	10/711,154	**Examiner:**	Speer, Timothy M
Filed:	08/27/2004		
Docket No.:	A382-USA		
For:	Material and Method to Prevent Low Temperature Degradation of Zirconia in Biomedical Implants		

Please see the attached retransmission of an Amendment faxed to the USPTO earlier today for the above case. The signed certifications on the first two pages were inadvertently omitted from the original fax transmission.

If you do not receive this transmission in its entirety please call 661-702-6773.

AMENDMENT TRANSMITTAL LETTER			Attorney Docket No: A382-USA
Application Serial Number: 10/711,154	Filing Date: 8/27/2004	Examiner: Timothy M. Speer	Art Unit: 1775

Invention: MATERIAL AND METHOD TO PREVENT LOW TEMPERATURE DEGRADATION OF ZIRCONIA IN BIOMEDICAL IMPLANTS

TO THE COMMISSIONER FOR PATENTS:
Transmitted herewith is an amendment in the above-identified application. The fee has been calculated as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	NO. OF EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	7	MINUS	12	0	$50	$ 0.00
INDEP. CLAIMS	2	MINUS	2	0	$200	$ 0.00
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT		

Charge $ 130.00 to Deposit Account 500692 for the attached Terminal Disclaimer.

12/6/05
Date

Gary D. Schnittgrund
Reg. No. 42130

I hereby certify that this Correspondence is being facsimile transmitted to the USPTO at 571-273-8300 on December 6, 2005.

Oleh Zajac

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jiang	**Art Unit:**	1745
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VIA FACSIMILE 571-273-8300

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited via facsimile to: Commissioner for Patents, facsimile number 571-273-8300, on:

Dec. 6, 2005

Glen Zajac

AMENDMENT

Dear Sir:

In response to the Office Action of November 18, 2005, please amend the above-identified application as follows:

INTRODUCTORY COMMENTS

Claims 1–12 are pending in the parent application. Claims 6–12 are withdrawn in accord with a provisional election with traverse by Applicant on about October 27, 2005.

Claims 1-4 are rejected under 35 USC 103(a) as being unpatentable over Schubert in view of Hida.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Schubert in view of Hida and further in view of Toibana.

A provisional obviousness-type double patenting rejection is raised to claim 1 relative to co-pending Application No. 10/853,922.

New claims 13 and 14 have been added.

Informal Comments

While it may not be relevant to the instant Office Action, Applicant's review of the PAIR File History reveals several likely errors which are called to the Examiner's attention:

"Information Disclosure Statement considered" on 9/2/04 and 8/27/04 may be incorrect dates since the IDS was dated 10/05 by the Examiner.

Oath or Declaration Filed 08/07/04 may be an incorrect date since the application was not filed until 08/27/04.

SPECIFICATION

The title and the Abstract are amended to reflect the effect of the restriction requirement, which eliminates the method claims.

CLAIMS

Claim 1 is amended to correct an editing error by deleting the double word "comprising".

Claims 6-12 are cancelled in accordance with the restriction requirement.

New claims 13-14 are added to claim the moisture resistant coating on the substrate.

DISCUSSION

Provisional Obviousness-type Double Patenting Rejection

The provisional obviousness-type double patenting rejection raised to claim 1 relative to co-pending Application No. 10/853,922 is addressed by filing a terminal disclaimer.

Product-by-Process Claim 1 Process Limitation

The Examiner states at page 3 of the Office Action, that "Regarding the recitation of the process limitation 'ion beam assisted deposition,' this limitation is being given no patentable weight, since an invention recited in a product-by-process claim is a product and not a process. The method by which a claimed product may be made is not germane to patentability of the claimed product unless applicant demonstrates that the recited process step produces a material different product. In the present case, no such evidence has been adduced." Applicant disagrees and argues that the phrase is a limitation as follows:

1. Applicant has demonstrated that the recited process step produces a materially different product. The ion beam assisted deposition process (IBAD) discussed in the Application [para 17] is described as creating a conformal coating versus alternative routes that result in a significantly different coating. It is disclosed that the resulting alumina coating is dense and strongly adherent to the Y-TZP substrate. The products of the IBAD formed coating are discussed further [para 20] when it is disclosed that the preferred alpha-alumina composition phase is thus formed. It is further disclosed [para 21] that the IBAD alumina coating offers excellent resistance to moisture penetration and diffusion (i.e., it is hermetic).

2. The Examiner offers no authority in support of the conclusion that the limitation to IBAD coating should be given no patentable weight. The claim is in an allowable form [MPEP2173.05p] and, as argued below, it is a limitation. Applicant asserts that it is clear that the claim is directed to the product and not the process, and is therefore allowable.

3. It is known and relied on that the Federal Circuit ruled that "process terms in product-by-process claims served as limitations in determining infringement." *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 835, 846-47 (Fed. Cir. 1992). In the claim, "The molded innersole produced by the method of claim 1[.]" the court held that the same innersole would not infringe unless the method of claim 1 were used in its manufacture.

Therefore, Applicant argues that the limitation to IBAD should be given patentable weight in considering the allowability of claim 1.

The Rejection of Claims 1-4 on Schubert and Hida is Overcome

Schubert is distinguishable from Applicant's invention. In the instant application it is taught to apply a coating of a dissimilar material, namely alumina, to a formed and densified yttria-stabilized tetragonal zirconia polycrystal substrate. Schubert, on the other hand, teaches converting the surface of the yttria-containing tetragonal ZrO_2 polycrystals [i.e., Y-TZP] during densification by sintering in a powder bed of stabilizing oxides, such as yttria, ceria, calcia and magnesia. Schubert places a green (i.e., unfired) Y-TZP compact in a powder bed and heats it, thereby converting the surface of the Y-TZP compact into a stabilized phase. This is done *in situ* converting of the surface of the compact and not by applying a coating and not by employing a coating process. Schubert does not teach a coating at all. Schubert does not teach alumina at all. It is important to note that alumina is not a stabilizing oxide according to Schubert. The process taught by Schubert is inapplicable to deposition or utilization of alumina to form a coating at all. Alumina does not convert the surface of Y-TZP to a stabile phase, even if the process taught by Schubert is employed. Ultimately, there is no product that Schubert teaches having either an alumina coating or stabile surface phase that contains alumina.

The properties of the surface phase disclosed by Schubert are not relevant to the discussion since the materials disclosed by Schubert and those claimed by Applicant are distinguishable. Applicant does not teach a stabile phase of zirconia, he teaches a coating of alumina on a stabile or partially stabile phase of zirconia.

Hida teaches a SIALON composition. The invention taught by Applicant is distinguishable over Hida. Hida teaches a composite material containing alumina, silicon, and a beta-sialon of the formula $Si_{6-z}Al_zO_zN_{8-z}$, where z is from 2.5 to 3.5. There is no zirconia or zirconium in the material taught by Hida.

Hida does not teach the formation of a stabile zirconia as taught by Applicant. In the section entitled, "Use of the beta-SIALON Material as a Sintering Aid", Hida teaches the use of the SIALON as an additive to aid in sintering of various ceramics, such as cordierite, mullite, and alumina, for example. Specifically at col 27, lines 1-4, Hida teaches the use of the SIALON as an additive to aid in sintering of zirconia. At col 27, lines 5-8 Hida teaches that the SIALON sintering aid produces a sintered zirconia body with improved properties. The suggestion by Hida at col 27, lines 1-4 that, "...the ceramic material to be sintered is zirconia which, preferably, has been partially stabilized with stabilizers such as alumina, magnesia, calcia, yttria, ceria, and the like" is unclear, cannot be interpreted by Applicant, and is nonsense. Hida proposes using SIALON as a sintering aid to form a stabile zirconia. Hida teaches that the zirconia has been partially stabilized with alumina, magnesia, calcia, yttria, ceria, and the like. How the zirconia became stabilized before sintering is not taught and defies normal materials processing.

Further, alumina is not a stabilizer for zirconia, while magnesia, calcia, yttria, and ceria are. What is meant by the phrase "and the like" is unknown. There are a limited number of material additives that combine to form stabile phases of zirconia and they do not include alumina. How Hida formed an alumina stabile phase of zirconia to be sintered and then sintered with SIALON as a sintering is not taught and defies good science.

Applicant finds no clarification or teaching in Hida to lend credibility or credence to the use of alumina as a phase stabilizer in zirconia.

Even if Hida does possess an alumina stabilized zirconia, this is distinguishable from the teaching of Applicant, which teaches an alumina coating on yttria stabilized zirconia. The zirconia taught by Applicant is not stabilized with alumina and contains no alumina.

<u>The Rejection of Claim 5 on Schubert and Hida and Toibana Is Overcome</u>

Claim 5 is allowable as further limitation on an allowable claim 1. The use of yttria to stabilize the phase transformation of zirconia is well known to those

skilled in the art. Addition of 3 mole percent yttria is within a commonly accepted range and limits the yttria addition to this concentration. Claim 5 limits an allowable claim and is therefore allowable.

In view of all of the foregoing, it is respectfully submitted that the pending claims 1-5 and 13-14 are allowable as amended and in the present application. Reexamination and allowance are respectfully requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California area telephone number (661) 702-6814 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

12/6/05
Date

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